REMARKS

Please reconsider this application in view of the above amendments and the following remarks. Claims 1-22, 24, 25, and 27-39 are pending. Claims 1-25 and 27-39 are rejected. Claims 1, 10, 24, 27-29, 32, and 38 are amended. Claim 23 is canceled.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 1-9 under 35 U.S.C. section 112, first paragraph, as failing to comply with the written description requirement.

Claim 1 has been amended to recite "the pressure and temperature in the chamber are less than the critical pressure and temperature of the solvent during the coating of the stent." Claim 1 is fully supported by the specification as-filed. The specification discloses at paragraph 5 coating of a stent by applying a composition including a polymer dissolved in a solvent and a therapeutic substance dissolved or dispersed in the solvent. Paragraph 5 also discloses the "solvent is allowed to evaporate to form the coating." The specification further teaches at paragraph 18 that "increasing the pressure ... above ambient pressure causes the solvent to evaporate more slowly leading to a coating with a smoother surface." Forming a coating through evaporation of a solvent requires the coating conditions to be below the critical point of the solvent since a substance at super critical conditions does not exhibit a liquid-gas phase transition, and thus, does not evaporate. Please remove the rejection of claims 1-9.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 10-20 and 32 under 35 U.S.C. section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner indicates that claim 10 is rendered contradictory with line 4 stating "less than ambient pressure" and lines 7/8 stating "greater than ambient pressure." Claim 10 recites "adjusting the pressure of the chamber to a pressure greater than ambient pressure." Please remove the rejection of claims 10-20.

The Examiner indicates that claim 32 contradicts claim 31 since claim 31 requires the presence of a therapeutic substance. Claim 32 recites "the composition comprises a polymer dissolved in the solvent and the therapeutic substance added thereto." Please remove the rejection to claim 32.

Rejections under 35 U.S.C. § 102

The Examiner has rejected Claims 10-39 under 35 U.S.C. section 102(e) as being anticipated by Mehta et al. (US 2002/0051845).

Claims 10-20

Claim 10 recites "applying a composition comprising a solvent to the implantable device while the device is disposed in an environment having the pressure at greater than ambient pressure, the coating is formed on the device through evaporation of the solvent."

Mehta et al. teaches contacting a "stent or other medical device with a liquid coating solution with a liquid coating solution comprising a film forming biocompatible polymer and an optional therapeutic agent in a solvent under super critical temperature and pressure, such that the polymer and therapeutic agent are solubilized under the super critical conditions but insoluble under sub-critical conditions." (Mehta et al., paragraph 8) Mehta et al. then teaches "reducing the pressure and/or temperature conditions to sub-critical levels to deposit a thin film coating of said polymer and optional therapeutic agent on the stent or other medical device." (Mehta et al., paragraph 9) The coating is deposited since the coating material becomes insoluble in the solvent at sub-critical conditions.

Mehta et al., therefore, teaches forming a coating through precipitation or deposition of coating material from a solvent onto a stent, not through evaporation of the solvent. Furthermore, adjusting temperature and pressure of the solvent to supercritical conditions, as disclosed in Mehta et al., does not allow formation of a coating through evaporation since a substance at super critical conditions does not exhibit a liquid-gas phase transition, and thus, does not evaporate. Therefore, Mehta et al. does not teach the limitation "the coating is formed on the device through evaporation of the solvent." Claims 11-16 and 20 depend from claim 10

and are allowable for at least the same reason that claim 10 is allowable. Please remove the rejection of claims 10-16 and 20.

Furthermore, as discussed below in reference to claim 21, claims 14-16 are independently patentable.

Claims 17-19 depend from claim 1. Claim 1 is allowable over the cited prior art. Thus, claims 17-19 are allowable for at least the same reason that claim 1 is allowable. Please remove the rejection of claims 17-19.

Claims 21-30

Claim 21 recites "the act of applying comprises spraying the composition on the implantable device." As indicated above, Mehta et al., teaches forming a coating by contacting a a device with a solvent including coating material at super critical conditions of the solvent followed by deposition of coating material from the solvent onto the device. Nowhere in Mehta et al.'s discussion of this method of coating does Mehta et al. discuss the use of spraying a composition onto a device, e.g., paragraphs 8-9, 50-55, and examples, paragraphs 56-72.

The Examiner states that "the deposition of the coating on the stent or other medical devices is equivalent to a spraying application (paragraph 13, 25, 51)." However, Mehta et al. teach exactly the opposite, i.e., the deposition method of Mehta et al. is not equivalent to spraying. Mehta et al. discuss spray coating of stents in the Background at paragraphs 4 and 5. However, Mehta et al. clearly teach against the use of spray coating in these paragraphs by pointing out the disadvantages of spray coating, for example, "spray coating can be problematic in that there is a significant amount of spray lost during the process and many of the pharmaceutical agents that one would like to incorporate in the device are quite costly." (paragraph 4 of Mehta et al.)

The coating method disclosed, for example, in the cited paragraphs above is clearly meant as an alternative and an improvement to spray coating. This is made even more evident from Mehta et al.'s statement in paragraph 4 "there is a continuing need for new and improved stent coating techniques." Furthermore, there is no teaching in Mehta et al. of the use of spray

coating a stent in combination with the methods discussed in the cited paragraphs which describes conditions above ambient pressure.

Thus, the combination of the two limitations of claim 21 (1)"applying a composition comprising a solvent and ... while the device is disposed in an environment having the pressure at greater than ambient pressure" and (2)"the act of applying comprises spraying the composition on the implantable device" are not taught by Mehta et al. Even if spraying were equivalent to deposition, claim 21 is not anticipated by Mehta et al. since the a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP Section 2131. Additionally, "the identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and MPEP Section 2131. Not only is "equivalent" not the same as "identical," the combination set forth above is simply not "found, either expressly or inherently" in Mehta et al., which is required for there to be anticipation.

Even if "deposition" were equivalent to "spraying," applicant is unaware of any statutory or case law which supports the Examiner's position that anticipation can be based on prior art disclosure of "equivalent" features or elements, outside of the context of means- or step-plus-function claim elements. Claim 21 does not contain means- or step-plus-function elements. Should the Examiner maintain the rejection of claim 21, applicant respectfully requests the Examiner cite such authority supporting the rejection.

Thus, claim 21 is allowable. Claims 22, 24, 25, and 27-30 depend from claim 21 and are allowable for at least the same reason that claim 21 is allowable. Please remove the rejections of claims 21, 22, 24, 25, and 27-30.

In addition, for the reasons discussed above with respect to claim 21, claims 27 and 28 are independently patentable.

Claims 23 and 26 are canceled.

Claims 31-39

Claim 31 recites "the pressure is selected based on the vapor pressure of the solvent." In Mehta et al., the pressure and temperature are adjusted based on the critical point of the solvent

since the coating material is soluble above and insoluble below the critical point. In addition, at supercritical conditions, a substance does not even have a vapor pressure. Thus, Mehta et al. do not teach the above-mentioned feature of claim 31. Claims 32-39 depend from claim 31 and are allowable for at least the same reason that claim 31 is allowable. Please remove the rejections of claims 31-39.

Furthermore, as discussed above in reference to claim 21, claims 35-37 are independently patentable.

Since all claims are allowable, please issue a Notice of Allowability directed at these claims.

If I can be of any help, please contact me.

Respectfully submitted,

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